UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

GRACEWAY PHARMACEUTICALS, LLC, and 3M INNOVATIVE PROPERTIES CO., **Plaintiffs,** **v.** **PERRIGO COMPANY, PERRIGO ISRAEL PHARMACEUTICALS LTD., and NYCOMED U.S. INC.,** **Defendants.**	**Civil Action Number: 2:10-cv-937** **OPINION** **HON. WILLIAM J. MARTINI**

OPINION

I. INTRODUCTION

This law suit is brought by Plaintiffs Graceway, LLC, (Graceway), founded in 2006, and Plaintiff 3M Innovative Products Co., ("3M IPC"). Three distinct patents are involved in this lawsuit.

First, the '338 Patent, (Patent No. 4,698,338), covers imiquimod, the active pharmacological ingredient in Aldara, a product originally approved by the Food and Drug Administration, ("FDA"), in 1997. Aldara is Graceway's core product, a mature product which it acquired in 2006 from 3M IPC. The '338 Patent expired on August 25, 2009, with a period of exclusivity which ran to February 25, 2010.

Second, Graceway also holds the '944 Patent, (Patent No. 5,238,944), or a license

thereunder, a formulation of imiquimod with isostearic acid. This patent was approved on August 24, 1993, and will expire on August 24, 2010, with a period of exclusivity running to February 24, 2011. The '944 Patent covers Aldara.

Third, Plaintiff 3M IPC is the owner of the '672 Patent, (Patent No. 7,655,672), with Graceway holding an exclusive license. This patent was issued on February 2, 2010. It protects a formulation of imiquimod and oleic acid. Graceway markets no product in the United States covered by the '672 Patent.

On January 10, 2007, Nycomed informed Graceway by letter that it had filed an Abbreviated New Drug Application, ("ANDA"), to produce a bioequivalent generic version of Aldara. Graceway understood this to mean that Nycomed would manufacture, use, offer for sale, etc., its product after Nycomed received FDA approval for its ANDA and after the '338 Patent on imiquimod had expired on February 25, 2010. On February 25, 2010, the FDA approved Defendant Nycomed's ANDA application seeking to produce a generic of Aldara, albeit one with a different formulation from Aldara. Nycomed's bioequivalent of Aldara, i.e., "Nycomed's Product," has been determined by the FDA to be a bioequivalent of Aldara, with both products functioning as creams for application to dermal or mucosal surfaces for delivery of imiquimod. Once approved, Nycomed immediately began advertising, selling, and distributing its product domestically. It is not disputed that Nycomed's Product does *not* infringe either the '338 Patent (which is now expired) or the '944 Patent (covering a formulation using isostearic acid). Nycomed's Product, like the formulation described in the

'672 Patent, makes use of a formulation of imiquimod and oleic acid (or super-refined oleic acid).

In a Complaint filed on Tuesday, February 23, 2010, Graceway alleges that Nycomed's Product infringes the '672 Patent and seeks damages and (preliminary and permanent) injunctive relief for the injury it has and will sustain in consequence of lost sales and profits of Aldara (a bioequivalent of Nycomed's Product), including lost reputation and market share, and lost business opportunities associated with an inability to fund current research ventures, including meeting payroll, and, perhaps, debt service. However, Graceway did *not* file a motion for a temporary restraining order at this time. The Court notes that during this week the east coast of the United States was inundated with a severe snowfall, in consequence of which the Court of the District of New Jersey closed early on Thursday, February 25, 2010 and was entirely closed on Friday, February 26, 2010: although attorneys of record were nevertheless able to make filings on the Court's docket – which would be automatically available to their opponents – through the CM/ECF system. On Sunday, February 28, 2010, Graceway filed a motion seeking a temporary restraining order against Nycomed (although not against the two Perrigo defendants appearing on the caption to the Complaint).

On March 2, 2010, this case was reassigned by Chief Judge Garrett E. Brown, Jr. to me (William J. Martini) after having been initially assigned to Judge Susan D. Wigenton. A hearing was held the next day, on March 3, 2010.

For the reasons elaborated below, the Court will **DENY** Plaintiffs' Motion for a Temporary Restraining Order, (Doc. No. 17).

II. FACTS AND PROCEDURAL POSTURE

3M IPC applied for the '672 Patent on or about December 12, 2004. Ultimately, the '672 Patent was approved on February 2, 2010. Graceway holds an exclusive license under the '672 Patent. The '672 patent makes use of a formulation including imiquimod and oleic acid. Aldara by contrast, protected under the '944 Patent makes use of a formulation including imiquimod and isostearic acid. Sales from Aldara is Graceway's primary revenue stream.

On or about January 10, 2007, Nycomed filed ANDA No. 78-548 seeking to produce a product bioequivalent to Aldara, but making use of an imiquimod and oleic acid formulation. Nycomed sent Graceway a notice letter ("Nycomed's Notice Letter"), to this effect. Notwithstanding the '338 Patent (now expired) and the '944 Patent (covering an isostearic acid formulation, as opposed to the oleic acid formulation in Aldara), the FDA approved Nycomed's ANDA on February 25, 2010. Apparently, Nycomed immediately began advertising and distributing its product and has sought to exploit the 180 day period of market exclusivity for the first generic on the market. Prior to February 25, 2010, Graceway had made some efforts to stop FDA approval of Nycomed's ANDA through the citizens' petition process. The FDA denied Graceway the relief it sought through the citizens'

petition process on or about January 26, 2010, and, again, on February 24, 2010.

Plaintiffs allege that Nycomed's Product infringes the '672 Patent, which was approved on February 2, 2010. Plaintiffs seek relief, including damages and injunctive relief, in regard to lost sales of Aldara, which is ***not*** protected by the patent in suit. Plaintiffs filed this action, on February 23, 2010, ***three full weeks*** after the '672 Patent was approved. Furthermore, Plaintiffs filed this action ***one*** day prior to the FDA's denying Graceway's second citizens' petition, and ***two*** days prior to the FDA's approving Nycomed's ANDA application, and ***two*** days prior to the expiration of the '338 Patent (covering imiquimod). However, Plaintiffs' motion for a temporary restraining order was not filed until Sunday, February 28, 2010, effectively, Monday, March 1, 2010: ***one day short of one full calendar month*** after the '672 Patent had been approved.

III. LEGAL STANDARD

The legal standard for granting a temporary restraining order is well-settled. "The four factors relevant to the district court's decision to grant or deny a preliminary injunction are (1) the likelihood of the patentee's success on the merits; (2) irreparable harm if the injunction is not granted; (3) the balance of hardships between the parties; and (4) the public interest." *Abbott Laboratories v. Andrx Pharmaceuticals, Inc.*, 473 F.3d 1196, 1200-01 (Fed. Cir. 2007). The adequacy of money damages appears to be a factor to be considered in deciding whether or not harm is irreparable. Furthermore, in reaching a determination under

this standard, the Court applies well-established equitable principles and standards. *Cf. eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 393 (2006) (precluding, in the permanent injunction context, the use of "expansive principles" to "broad swath[es] of cases" or the use of "general rule[s] ... unique to patent disputes," apart from the four-factor test).

The parties dispute the legal standard in regard to two points. Plaintiffs assert that a sliding scale approach applies to two factors: irreparable harm and success on the merits. In other words, the more the movant clearly establishes one of these two factors, the less of a showing the movant need make in regard to the other and vice versa. Defendant disputes this. *See, e.g.*, *Qingdao Taifa Group Co. v. United States*, 581 F.3d 1375 (Fed. Cir. 2009). Secondly, the parties dispute whether *eBay*, *supra*, eliminated the rebuttable presumption of irreparable harm that follows a judgment of validity and infringement. *See generally Amado v. Microsoft Corp.*, 517 F.3d 1353, 1359 n.1 (Fed. Cir. 2008) (leaving the existence of the "rebuttable presumption" as an open question); *Broadcom Corp. v. Qualcomm Inc.*, 543 F.3d 683, 702 (Fed. Cir. 2008) (same) (quoting *Amado*, *supra*); *Automated Merchandising Systems, Inc. v. Crane Co.*, C.A. Nos. 2009-1158, 2009-1164, 2009 WL 4878643, at *3 (Fed. Cir. Dec. 16, 2009) (NOT PRECEDENTIAL) (holding that post *eBay* "the presumption of irreparable harm, based just on proof of infringement [has been] discarded"). The Court has considered these fine distinctions and has determined that nothing in this decision hinges on either of them. As explained more fully below, whether or not the rebuttable presumption of irreparable harm continues post-*eBay*, the Court finds, based on Plaintiffs' dilatory conduct,

that the rebuttable presumption, to the extent it still exists, has been rebutted.

IV. ANALYSIS

A. Threshold Defenses

Before turning to the traditional four-factor test, the Court analyzes two threshold defenses put forward by Defendant Nycomed.

1. May Plaintiffs Seek Protection Under The Patent Law For Loss Of Market Share And Profits Associated With Plaintiffs' Product, Although That Product, Aldara, Is Not Protected By The Patent In Suit?

Defendant Nycomed argues that because Plaintiffs do not practice the '672 Patent, they cannot seek relief in regard to its violation, particularly where, as here, the harm accruing to its infringement relates to lost sales of a non-infringed product, i.e., Aldara. It appears to the Court that Nycomed's position was rejected by (a divided *en banc* decision of) the Federal Circuit in *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538 (Fed. Cir. 1995). In *Rite-Hite*, the plaintiff held a patent on a product which it did not manufacture, and it manufactured an unpatented product. When a competitor infringed the patent, the court awarded damages for lost sales to its unpatented product. *Id*. at 1548. The *Rite-Hite* court reasoned that "but for" the existence of the infringing product, the patent holder would not have lost sales to its non-patented product, a product in competition with the illegally infringing product. *Id*. at 1546. This Court sees no reason to believe that if damages in such circumstances are proper, why injunctive relief might not also be available assuming the

standard showing is made by the movant in support of injunctive relief. *But see id*. at 1556 (Nies, J., dissenting) (issuing a powerful dissent); *but cf. Broadcom Corp.*, 543 F.3d at 702 (affirming grant of injunctive relief to vindicate interest in a competitive product where infringement was to an unpracticed product in the context of a market driven by "design wins," as opposed to a market driven by competition for sales which are on a "unit-by-unit" basis). Unlike the authority discussed above, the counter-authority Nycomed points to in its briefs is not binding Federal Circuit authority.

2. Unjustified Delay, Dilatory Conduct, And Laches

It is altogether possible that after a full trial on the merits, this Court may find that Nycomed has infringed on Plaintiffs' '672 Patent. Likewise, it is altogether possible that this Court may determine that that patent is enforceable. But a legal right against infringement, even where established, does not, without more, establish a right to injunctive relief. Injunctive relief, particularly preliminary injunctive relief, based on a limited record, is, as all authorities acknowledge, not a matter of mere legal right, i.e., preliminary injunctive relief is not a "standard remedy;" rather is a form of "extraordinary" relief. *Eli Lilly & Co. v. Am. Cyanamid Co.*, 82 F.3d 1568, 1578 (Fed. Cir. 1996). Such a remedy will not be granted "whenever the plaintiff has shown a likelihood of success on the merits," *id*., nor will it be granted in the face of a movant's inequitable conduct, including laches, i.e., unjustified delay or dilatory conduct. *See, e.g*., *Intirtool, Ltd. v. Texar Corp*., 369 F.3d 1289, 1290 (Fed. Cir. 2004) ("The laches defense has two underlying elements: first, the patentee's delay in

bringing suit must be unreasonable and inexcusable, and second, the alleged infringer must have suffered material prejudice attributable to the delay." (quotation marks omitted)).

Plaintiff Graceway unjustifiably delayed notifying Nycomed of its legal exposure and otherwise unjustifiably delayed bringing this suit in three distinct ways. First, Nycomed filed its ANDA in January 2007. Between January 2007, when Graceway received Nycomed's Notice Letter, and February 2, 2010, when Graceway's '672 Patent was approved, ***a three year period***, Graceway never, as far as the record discloses, put Nycomed on notice that Nycomed's planned future production of its bioequivalent of Aldara may infringe Graceway's then-pending '672 Patent (once approved).[1] Plaintiff was not legally obligated to notify Graceway in this manner. But Graceway's failure to do so, or to unambiguously indicate that it would pursue all its legal rights without fail in order to block the sale of Nycomed's Product, its strategic silence, left Nycomed in a position in which it continued to pursue its ANDA and to put its product in readiness of ultimate FDA approval and commercial launch: all costly enterprises. This is not to say that Graceway's behavior leaves it without a damages remedy – a wholly separate question – but it undermines its claim for "extraordinary" relief. Graceway knew Nycomed's Product would infringe its (allegedly) valid patent, but it did not tell Nycomed until Nycomed incurred costs. Those sunk costs are not just losses to Nycomed and its stockholders, but to society at large. *See also infra*

[1] *See* Klaum Aff. ¶ 10 (affirming that Nycomed was not on notice in regard to any pending patent prior to Plaintiffs' bringing this suit). Klaum's position is unrebutted by any record evidence reflected in Plaintiffs' memoranda of law.

Part IV[B][4] (weighing the public interest).

Second, why was not suit brought on February 2, 2010, the date Graceway's '672 Patent was approved? (Or, in lieu thereof, why was no notice letter sent to Nycomed on February 2, 2010?) And why did Plaintiffs delay until February 23, 2010? As early as February 2, 2010, Graceway knew that Nycomed's Product, once the ANDA was approved, would infringe its (allegedly) valid '672 Patent. The record does not reveal that Graceway pressed its rights. It did not promptly send a letter to Nycomed clearly asserting its legal rights and offering to litigate (or to arbitrate) this dispute prior to Nycomed's marketing its product. As such Nycomed's business plans went ahead unchecked for three further weeks. Indeed, this litigation puts at risk Nycomed's right to a 180 day monopoly for bringing the first generic to market: a very valuable statutory right. Had Nycomed received more timely notice of its litigation risk, it might have delayed.

When pressed at oral argument to account for the post-February 2, 2010 delay, counsel for Plaintiffs argued that had if it had brought suit earlier, the law suit may have been "premature." Trans. 6:23, 11:5 (March 3, 2010). In other words, Plaintiffs did not assert – in order to account for the delay – that they only became aware that Nycomed's product infringed the '672 Patent on or after February 2, 2010. Rather, Plaintiffs' attorney made reference to the fact that on February 23, 2010, the ANDA had not yet been approved, its second citizens' petition was still pending, and the '338 Patent was still in-force. This argument cuts ***against*** Plaintiffs. If Plaintiffs had Article III standing, ostensibly based on

genuine adverse interests and imminent harm, to bring this suit against Nycomed on February 23, 2010, at a time two days ***prior*** to the expiration of the '338 Patent, two days ***prior*** to Graceway's ANDA's approval by the FDA, and one day ***prior*** to the rejection of its second citizens' petition, then Plaintiffs also had standing to bring this suit prior to these events on February 2, 2010. In other words, if Plaintiffs' suit was not timely until the '338 Patent had expired, until the ANDA had been approved, and until its second citizens' petition had been rejected, then even this suit was clearly premature. The fact that Plaintiffs brought this suit prior to those three events means that they believed they had standing to do so, and if they had standing to bring suit one or two days prior to these events, then this Court can see no reason why they did not have sufficient standing to bring suit twenty-one days prior on February 2, 2010 when the '672 Patent was approved.

Third, once Plaintiffs decided to bring suit on February 23, 2010, why did they delay (yet again) until February 28, 2010 to file their motion for a temporary restraining order? Nothing seems to account for this further delay. (Again, the Court acknowledges that this Court closed early on February 25 and was closed on February 26, 2010 – but attorneys were free to file and serve papers on CM/ECF on both these days in spite of the snow.)

Even leaving aside the initial three year period starting with Nycomed's Notice Letter, Plaintiffs delayed one day short of a full calendar month to press their rights. *See Hart Intercivic Inc. v. Diebold, Inc.*, Civil Action No. 09-678, 2009 WL 3245466, at *8 (D. Del. Sept. 30, 2009). To be clear, the number of days involved, standing alone, is not

determinative, although an unexplained three to four week delay, as here, hardly counts in Plaintiffs' favor. Here, the multiple delays are unexplained; they are – to all appearances – unreasonable. (To the extent that they were taken to catch an opponent at unawares, not an unreasonable assumption given the lack of explanation, they further undermine Graceway's entitlement to extraordinary relief.) Moreover, this litigation puts at risk Nycomed's 180 day monopoly for first generic on the market: Nycomed put its product on the market ***prior*** to Plaintiffs' filing their motion for a temporary restraining order. Nycomed has also incurred the costs associated with its putting its product in the stream of commere during the period of time ***prior*** to Plaintiffs' filing their motion for a temporary restraining order. This is a sufficient showing to satisfy the standard laid down by the Federal Circuit in *Intirtool, Ltd.*, 369 F.3d . *See also Nutrition 21 v. United States*, 930 F.2d 867, 872 (Fed. Cir. 1991) (holding that a "substantial period of time before seeking a preliminary injunction at least suggests that the *status quo* does not irreparably damage" the movant seeking an injunction). For all these reasons, it appears that Nycomed's laches defense succeeds.

B. The Four Factor Test For Injunctive Relief

1. The Likelihood Of The Patentee's Success On The Merits

At trial, the burden is on the alleged infringer to show by clear and convincing evidence that the patent is not valid. *See American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1359-60 (Fed. Cir. 1984). However, this is not the governing standard in regard to validity at the preliminary injunction stage, the stage which interests us here. At

this stage, the party seeking to oppose injunctive relief "must [only] show a substantial question of invalidity to avoid [the movant's] showing [a] likelihood of success." *Erico Intern. Corp. v. Vutec Corp.*, 516 F.3d 1350, 1354 (Fed. Cir. 2008). Nycomed argues that the '672 is invalid for obviousness.

The '672 Patent was filed in December 2004. At the time the United States Patent and Trademark Office, ("USPTO"), examined the '672 Patent, the Patent Officer considered prior art, including the '944 Patent (discussing oleic and isostearic acid, as possible solvents, ultimately preferring isostearic acid), the Chollet Article, (Banker Aff. Ex. C), and super refined oleic acid, ("SROA"), as a substitute for oleic acid (*id*. Ex. D). The USPTO considered this prior article and SROA-related literature, but issued the '672 nonetheless.

Notwithstanding the decision of the USPTO, Nycomed asserts that the USPTO erred. It supports its assertions with two declarations put forward by experts. *See* Palmieri Decl. ¶ 5(d);[2] Banker Decl. ¶¶ 26-33.[3] Both of whom concluded that a person of ordinary skill in

[2] *See, e.g.*, Palmieri Decl. ¶ 5(d) ("One of ordinary skill in the art would find it obvious to combine the Chollet Article with Super Refined Oleic Acid, NF to arrive at the invention in the '672 Patent claims 1-20. This is especially true since it is standard practice in the field of pharmaceutical sciences to use the highest grade or purest form of an ingredient when formulating a pharmaceutical product. In fact, I have repeatedly taught this standard to my students for over 20 years.... Furthermore , because SROA is more pure than regular oleic acid, one of ordinary skill in the art would have a reasonable expectation that the substitution of SROA for the oleic acid used in the Chollet Article would be successful.").

[3] *See, e.g.*, Banker Decl. ¶ 33 ("[O]ne of ordinary skill in the art would have a reasonable expectation that substituting the more pure Super Refined Oleic Acid for the older oleic acid used in the Chollet Article would be successful, especially since the SROA has been stabilized by two mechanisms .... overcoming the potential limitations of the older oleic

the art would have found the '672 Patent obvious based on prior art: the Chollet article and known developments involving SROA. By way of response, Plaintiffs put forward no expert evidence, but merely stand on the findings of the USPTO. The Court has considered the expert evidence submitted by Nycomed. It has weight. Plaintiffs have submitted no contrary affidavits, much less any argument explaining the error in the reasoning put forward by Palmieri and Banker. In these circumstances, Nycomed has met its burden, i.e., it has raised a substantial question as to validity. Plaintiffs' position in regard to the enablement and written description requirement connected to validity seems similarly defective. Specifically, Nycomed argues that although the '672 Patent teaches how to test for imiquimod-related impurities, it does not describe or teach how to achieve the imiquimod-related impurities limitation. Nycomed's position is again supported by declarations. Plaintiffs' is not.

In all, Plaintiffs have raised a substantial question as to invalidity.

2. Irreparable Harm To Movant If The Injunction Is Not Granted

As explained in Part IV[A][2], *supra*, the Court has determined that Plaintiffs have unreasonably delayed bringing this action to the detriment of Nycomed. Such a delay is some indication that Plaintiffs are not irreparably harmed. *See Nutrition 21*, 930 F.2d at 872. The Court also notes that in the leading case awarding injunctive relief for injury to a competitive product which is not protected by the patent in suit, the Court awarded relief because the relevant market was characterized by "design wins." *Broadcom Corp.*, 543 F.3d

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acid cited in the Chollet Article.").

at 702. In the instant case, unlike *Broadcom*, the market is characterized by unit-by-unit competition. *See* Trans. 65:4-5 (March 3, 2010) (Attorney for Plaintiffs: arguing that damages should be calculated on a unit-by-unit basis – i.e., "every unit of their product that was sold [should be considered] a unit of our product [that was not sold]"). In this situation money damages can be calculated and such a calculation undermines the position that harm is irreparable. *See Rite-Hite Corp.*, 56 F.3d at 1548 (awarding a patent-holder lost profits for lost sales involving a non-patented product which suffers competitive injury in connection with patent infringement). Finally, "loss of market share and price erosion are economic harms and are compensable by money damages .... [even] in the context of generic competition in the pharmaceutical industry ...." *Novartis Pharms. Corp. v. Teva Pharms. USA, Inc.*, Civil Action No. 05-CV-1887, 2007 WL 2669338, at *14 (D.N.J. Sept. 6, 2007).

3. The Balance Of Hardships Between The Parties

The balance of hardships favors Nycomed. By not granting the injunction, Plaintiffs lose an extension of their monopoly in regard to Aldara, which is arguably extended by operation of the '672 Patent. The loss to Graceway effects its bottom line, its ability to fund new research, and perhaps its ability to service its debt obligations and pay its employees. Of course, to the extent that this is true, one can only wonder why it did not bring suit on February 2, 2010 and why it refused to clarify the legal position of the parties prior to that time. Graceway would argue that Nycomed ***voluntarily*** moved forward on February 23, 2010 even though Nycomed was warned that production of its product would

infringe Graceway's then-pending patent. But putting a competitor on notice two days before its intended launch while standing silently and in possession of full information for several years might lead a neutral observer to conclude that Graceway ***voluntarily*** took a risk and only acted on its patent rights once its concluded that its other legal options – relying on the FDA to not approve Nycomed's ANDA and relying on the FDA's citizens' petition process – were exhausted. Nycomed will also lose the benefit of its statutory 180 day monopoly for bringing the first generic to the market should its product be recalled by order of this Court. Nycomed will also be out the cost for readying its product for launch and launching it – all costs sunk ***prior*** to Plaintiffs' filing their motion for a temporary restraining order. Pulling Nycomed's product will also have an effect on its reputation, its commercial relationships, and, no doubt, on its employees' moral. Moreover, the lost profits (or royalties) owed Plaintiffs, should it be determined that the '672 Patent was infringed and enforceable, would seem to be calculable.

4. The Public Interest

The public interest is enhanced by enforcing valid patents: encouraging the development of new drugs through incentives connected to future profits from limited temporal monopolies. The public interest is also enhanced by competition: encouraging generic drugs to come onto the market the moment legal patent protection ends. Both interests are at stake here. However, there is no reason to believe that Nycomed was aware of the '672 Patent prior to February 2, 2010, the date it was issued. Nycomed might not even

have known of the existence of the '672 Patent until Plaintiffs launched this suit on February 23, 2010. Prior to that time, Nycomed had filed for an ANDA and spent millions of dollars to put its future generic in readiness to enter the stream of commerce once the '338 Patent expired on February 25, 2010.

Plaintiffs knew this because they opposed Nycomed's ANDA; indeed, Graceway raised safety concerns in regard to Nycomed's then-proposed bioequivalent product. The record shows that during this time Plaintiffs did nothing to put Nycomed on notice that Nycomed's expenditures towards its planned product would infringe Plaintiffs' then-pending patent. The patent it seeks to enforce here. Such strategic action might be legal, but it leads to needless litigation and costs, as this case proves.

More importantly, granting the motion for a preliminary injunction would lead to expenditures that are a dead weight loss to society if the manufacturer of the new product is enjoined from selling its product after being surprised by a patent approved a mere two days before its ANDA is approved. Certainly the monies spent by Nycomed would be a dead weight loss to society should this Court order Nycomed to retrieve all product it has put into the stream of commerce. In these circumstances, the public interest is not advanced by awarding a preliminary injunction. Throughout this entire process, Plaintiffs were the low cost actor, and, for that reason, they should have acted. *Compare* Stephen G. Gillies, *Negligence, Strict Liability, and the Cheapest Cost Avoider*, 78 VA. L. REV. 1291, 1336 (1992) ("[N]egligence ... involves acts that create foreseeable danger to others, and, as such,

is a form of cheapest cost-avoider analysis."), *with Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1221 (Fed. Cir. 1995) (describing patent infringement as a "tort").[4]

To put it another way, Plaintiffs could have made efforts to have clarified the parties' legal rights before Nycomed sunk costs and distributed its product. By delaying until after Nycomed sunk significant costs, Plaintiffs have burdened their opponent. Had they acted in 2007, there would be no need for any emergent motion. Had they even acted on or about February 2, 2010, the Court would have had three full weeks to develop a record and an opinion. Instead, Plaintiffs waited until after Nycomed's Product entered the stream of commerce and then moved for a temporary restraining order.

The public has a substantial interest in seeing that litigation like this is not brought again.

Having weighed the four factors, even apart from Nycomed's equitable defense of laches, the Court concludes that a preliminary injunction should not issue.

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[4] If Plaintiffs practiced the patent in suit, the equities might be different. Likewise, if Aldara were covered by the patent in suit, the equities might, again, be different. But here Plaintiffs are asserting competitive injury to Aldara and enforcing their rights based on a patent they do not practice. That is a very unusual fact pattern, if not an unforseeable one, that is, unforseeable from Nycomed's point of view. A plaintiff is allowed to plan its affairs in such ways, but if it does, the consequences should not fall on its less than omniscient competitor. Had Plaintiffs warned Nycomed earlier of the consequential risks it faced, then Plaintiffs would now be in a position to say they "d[id] Equity," as opposed to standing on their narrow legal rights. *See* JOSEPH STORY, COMMENTARIES ON EQUITY JURISPRUDENCE 1:77 (1836) (explaining that "he who seeks Equity, must do Equity"); 2 J. POMEROY, EQUITY JURISPRUDENCE § 385 (5th ed.1941) (same); *Gaston-Lincoln Transit, Inc. v. Maryland Cas. Co.*, 206 S.E.2d 155, 158 (N.C. 1974) (describing this principle as the "Golden Rule" and "fundamental principle" of equity jurisprudence).

V. CONCLUSION

For the reasons elaborated above, the Court **DENIES** Plaintiffs' Motion for a Temporary Restraining Order, (Doc. No. 17).

s/ William J. Martini
William J. Martini, U.S.D.J.

DATE: **March 8, 2010**